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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
STOCK JR, GORDON J

ART UNIT	PAPER NUMBER
2877	

DATE MAILED: 09/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/821,571	Applicant(s) MCCAFFREY ET AL.	
	Examin r Gordon J Stock	Art Unit 2877	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *43,58,59 and 62* is/are allowed.

6)☒ Claim(s) *1-3,7,30-32,57 and 60* is/are rejected.

7)☒ Claim(s) *4-6,8-29,33-42,44-56, 61* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 March 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2,4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Drawings and Specification

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: analog/digital converter, 30, in Fig. 2. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. Figure 2 is also objected to for the following informality: reference sign, 38, from the CPU is unclear. Correction is required. Figure 5 is objected to for the following informality: the typographical error in Box 56, "hight light." Correction is required.

2. Specification is objected to for the following informalities: on page 9 line 5 of paragraph 42 there lacks an application number to the application incorporated by reference.

Claim Objections

3. Claim 4 is objected to for the following: "the solid state switches" lacks antecedent basis. Claim 8 is objected to for the following: "the threshold value" lacks antecedent basis. Claim 9 is objected to for the following: "the fist light sensor" should read –the first light sensor--. Claim 12 is objected to for the following: "the transparent window" and "the consumable" lack antecedent basis. Claim 13 is objected to for the following: "the LED" lacks antecedent basis. Claim 14 is objected to for the following: "the open door" lacks antecedent basis. Claim 15 is objected to for the following: "the consumable" and "the sample compartment" lack antecedent basis. Claim 16 is objected to for the following: "the LED" and "the microprocessor" lack antecedent basis. Claim 17 is objected to for the following: "the LED" of line 2 and "the stored LED reference value," lack antecedent basis. Claim 18 is objected to for the following: "the LED" lacks antecedent basis. Claim 19 is objected to for the following: "the LED" lacks antecedent basis. Claim 21 is objected to for the following: "the LED" lacks antecedent basis. Claim 22 is objected to for the 333following:

"the solid state switches" and "the integration feedback capacitors" lack antecedent basis. Claim 25 is objected to for the following: "the first photodiode" lacks antecedent basis. Claim 27 is objected to for the following: "the first photodiode" lacks antecedent basis. Claim 30 is objected to for the following: "the sample chamber" lacks antecedent basis. Claim 34 is objected to for the following: "the ITO" lacks antecedent basis. Claim 35 is objected to for the following: "the first photodiode" and "the bandpass filter" lack antecedent basis. Claim 36 is objected to for the following: "the first photodiode" and "the first diode" lack antecedent basis. Claim 39 is objected to for the following: "the sample chamber" lacks antecedent basis. Claim 47 is objected to for the following: "the detection mode" and "the source of light" lack antecedent basis. Claim 49 is objected to for the following: "the consumable" lacks antecedent basis. Claim 50 is objected to for the following: "the hosing" of line 4 should read –the housing--. Claim 52 is objected to for the following: "the first mode" lacks antecedent basis. Claim 53 is objected to for the following: "the second mode" and "the second signal" lack antecedent basis. Claim 54 is objected to for the following: "the second signal" and "the third mode" lack antecedent basis. Claim 55 is objected to for the following: "the third mode" and "the second signal" lack antecedent basis. Corrections required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. **Claims 1-3, and 7** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Shanks et al. (4,810,658).**

As for **claims 1-3 and 7**, Shanks in a photometric instrument for luminescent properties discloses: a first light sensor generating a sample signal in detecting luminescence; a second light sensor shielded from the

luminescence and a generating a reference signal; and discloses controlling the output of the signals suggesting there is a controller comprising the analog/digital converter (Figs. 1 and 3; col. 8 lines 55-67; col. 9 lines 1-40). As for a resulting signal indicative of the sample as the difference between the sample and reference signals; and the device comprising switched integrators and outputting integrated values; and provided with respective integration bypass capacitors and solid state switches; comprising pair of analog to digital converters to digitize the sample and reference signals and subtracting the reference signal from the digitized sample signal, Shanks mentions the manipulation of the signals and processing of the signals through appropriate means (col. 8, lines 60-67; col. 1-20). As for software, Shanks is silent; however, the Examiner takes official notice that microprocessors are well known in the art for processing signals and that microprocessors comprise software in order to perform necessary functions. Therefore, it would be obvious to one skilled in the art at the time to have software in order to process the subtraction of the particular signals.

6. **Claims 30-32** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Collins et al. (6,579,722) in view of Northrup et al. (5,589,136).**

As for **claims 30-32**, Collins discloses the following: a housing provided with a sample compartment; a detection assembly in the housing for detecting the luminescence and generating a signal; a transparent window; a controller, computer, that determines whether a resulting signal processed is indicative of the presence of the sample; a chassis that is a conductive material, glass plate and glass substrate (Figs. 1a, 1b, 2; cols. 6-7). He is silent concerning a conductive layer on the window. Northrup in a chemical reaction chamber teaches using a conductive layer, indium tin oxide, on the window for to use as viewable electrode (col. 14, lines 55-65). Therefore, it would be obvious to one skilled in the art at the time to have a window of a sensor comprise indium tin oxide in order to pass for an electrode and for an optical channel to the detector for luminescence detection.

7. **Claims 57 and 60** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gustafson et al. (5,413,939).**

As for **claims 57 and 60**, Gustafson in a solid-phase binding assay system discloses: providing a first photoreceiver for generating a sample signal; providing a second photoreceiver for generating a reference signal; providing a controller for subtracting the reference from the sample signal; comparing the signal with a predetermined threshold; incrementally increasing the integration time if the resulting signal is less than the threshold and of monitoring the integration time (cols. 6-11). As for displays, Gustafson discloses using a microprocessor (col. 13, lines 55-60). The Examiner takes official notice that display devices are well known in the art in order to display the acquired data. Therefore, it would be obvious to one skilled in the art at the time the invention was made to have a display device in order to display the acquired data. As for photodiodes, Gustafson discloses CCDs (Fig. 10). However, photodiodes are well known in the art as devices to detect photons. Therefore, it would be obvious to one skilled in the art at the time the invention was made to use photodiodes, for photodiodes photodetect.

Allowable Subject Matter

8. **Claims 43, 58, 59, 62** are allowed. And **Claims 4-6, 8-29, 33-42, 44-56, and 61** are objected to as being dependent upon a rejected base claim or of having an objection as stated above, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and rewritten to overcome any objection as stated above. As to **claim 43**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a hand held assay device "a controller having an analytical mode, wherein the resulting signal is evaluated, and a detection mode, wherein the consumable-present signal is evaluated" in combination with the rest of the limitations of **claim 43.** As to **claim 58,** the prior art of record, taken alone or in combination, fails to disclose or render obvious in a method for detecting the presence of a sample "providing a film of a conductive plastic material on the transparent bottom, thereby minimizing the

direct injection of static charge," in combination with the rest of the limitations of **claim 58.** As to **claim 59**, the prior art of record, taken alone or in combination, fails to disclose or render obvious "generating a reference signal in response to detecting environmental changes" and the specific step of comparing the value in combination with the rest of the limitations of **claims 59 and 62.** As to **claim 4**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a hand held device the particular software, in combination with the rest of the limitations of **claims 4-6.** As to **claim 8**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a hand held assay device "calculating a logarithmic number of the resulting signal," in combination with the rest of the limitations of **claim 8.** As to **claim 9**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a handheld device "a calibration mode, wherein the cleanliness of the window is controlled" in combination with the rest of the limitations of **claim 9-11; 23-27.** As to **claim 12**, the prior art of record, taken alone or in combination, fails to disclose or render obvious a hand held assay device, "a sample compartment having a transparent window upstream from the first light sensor and a door spaced from the window" and a consumable in combination with the rest of the limitations of **claims 12-14; 28-29** As to **claim 15**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a handheld device "low, mid, and high levels and for determining if this signal is indicative of the presence of the consumable," in combination with the rest of the limitations of **claim 15-20.** As to **claim 21**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in 33a hand-held device the particular software, in combination with the rest of the limitations of **claim 21.** As to **claim 22**, the prior art of record, taken alone or in combination, fails to disclose or render obvious a handheld device the particular software, in combination with the rest of the limitations of **claim 22.** As to **claim 30**, the prior art of record, taken alone or in combination, fails to disclose or render obvious handheld assay device "said transparent window being covered with a conductive transparent coating," in combination with the rest of the limitations of **claims 30-38.** As to **claim 39**, the prior art of record, taken

alone or in combination, fails to disclose or render obvious in a handheld device "the detection assembly generating a calibration signal indicating cleanliness of the transparent window" in combination with the rest of the limitations of **claims 39-42, 44-49, and 51-56.** As to **claim 50**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a handheld assay device the first, second, and third modes, in combination with the rest of the limitations of **claim 50.** As to **claim 61**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a method of measuring the presence of a sample "the step of detecting a consumable," in combination with the rest of the limitations of **claim 61.**

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:
U.S. Patent 4,608,344 to Carter et al. U.S. Patent 5,358,691 to Clark et al.
U.S. Patent 5,422,075 to Saito et al. U.S. Patent 6,191,847 to Melendez et al.
U.S. Patent 6,325,978 to Labuda et al.

Fax/Telephone Numbers

If the applicant wishes to send a fax dealing with either a proposed amendment or a discussion with a phone interview, then the fax should:

1) Contain either a statement "DRAFT" or "PROPOSED AMENDMENT" on the fax cover sheet; and

2) Should be unsigned by the attorney or agent.

This will ensure that it will not be entered into the case and will be forwarded to the examiner as quickly as possible.

Papers related to the application may be submitted to Group 2800 by Fax transmission. Papers should be faxed to Group 2800 via the PTO Fax machine located in Crystal Plaza 4. The form of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CP4 Fax Machine number is: **(703) 308-7722**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gordon J. Stock whose telephone number is (703) 305-4787. The examiner can normally be reached on Monday-Friday, 10:00 a.m. - 6:30 p.m.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

gs
September 8, 2003

Zandra V. Smith
Primary Examiner
Art Unit 2877